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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,590	07/31/2006	Ira Sanders	LIN-001	3452

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EXAMINER	
HICKS, VICTORIA J	
ART UNIT	PAPER NUMBER
3772	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/597,590	SANDERS, IRA	
	Examiner	Art Unit	
	VICTORIA HICKS	3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-75* is/are pending in the application.

4a) Of the above claim(s) *19-31,41-47,58-65 and 70-73* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-40,48-57,66-69,74 and 75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 July 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/5/07, 1/14/08, 2/5/08, 8/14/08, 9/4/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to the amendment filed on August 13, 2009.

Claims 1-18 have been cancelled by Applicant.

Election/Restrictions

Applicant's election without traverse of claims 32-40, 48-57, 66-69 and 74-75 in the reply filed on 8/13/09 is acknowledged.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 32-34, 40, 48-52, 55, 57, 66, 68, 69, 74 and 75 are rejected under 35 U.S.C. 102(e) as being anticipated by Conrad et al. (US patent 7,237,554).

In regards to claim 32, Conrad et al. teaches in Figures 1 and 2 and column 3, lines 24-33 and 48-51 a shaft (12) sized for insertion into a soft tissue (T) located in a patient's oral cavity or pharynx; a retractor member (14) connected at or near a first end of the shaft; and an anchor member (18) connected at or near a second end of the

shaft, wherein at least one of the retractor (14) member and the anchor member (18) is configured to be positioned on an external surface of the soft tissue (T), and at least one of the shaft (12), the retractor member (14) and the anchor member (18) interact to exert a pressure that prevents deformation of the external surface that brings the soft tissue toward another soft tissue located in the patient's oral cavity or pharynx (the tongue base TB and soft palate trailing end T are retained from movement toward the pharyngeal wall PW).

In regards to claim 33, Conrad et al. teaches the apparatus of claim 32. Conrad et al. teaches in Figures 1 and 2 and column 3, lines 37 and 48-51 that the pressure (tension) stiffens the soft tissue to prevent deformation of the external surface (the tongue base TB and soft palate trailing end T are retained from movement toward the pharyngeal wall PW), the pressure (tension) is a counterforce pressure that prevents deformation of the external surface, the pressure is a counterforce pressure (tension) that creates an indentation in the external surface, or at least one of the retractor member (14), the shaft (12), and the anchor member (18) adjust to alter the pressure exerted on the soft tissue.

In regards to claim 34, Conrad et al. teaches the apparatus of claim 32. Conrad et al. teaches in column 3, lines 29-30 that the shaft (12) is flexible (suture material).

In regards to claim 40, Conrad et al. teaches the apparatus of claim 32. Conrad et al. teaches in Figures 1 and 2 a connection to the patient's oral cavity.

In regards to claim 48, Conrad et al. teaches in Figures 1 and 2 and column 3, lines 24-33 and 48-51 a shaft (12) sized for insertion into a patient's tongue (T); a

retractor member (14) connected at or near a first end of the shaft (12); and an anchor member (18) connected at or near a second end of the shaft (12), wherein at least one of the retractor member (14) and the anchor member (18) is configured to be positioned on an external surface of the tongue (T), and at least one of the shaft (12), the retractor member (14) and the anchor member (18) interact to exert a pressure that prevents the external surface from falling toward a soft tissue located in the patient's oral cavity or pharynx (the tongue base TB and soft palate trailing end T are retained from movement toward the pharyngeal wall PW).

In regards to claim 49, Conrad et al. teaches the apparatus of claim 48. Conrad et al. teaches in Figures 1 and 2 that the shaft (12) is sized for insertion through the patient's tongue (T).

In regards to claim 50, Conrad et al. teaches the apparatus of claim 48. Conrad et al. teaches in Figures 1 and 2 and column 3, lines 37 and 48-51 that the pressure (tension) stiffens the soft tissue to prevent deformation of the external surface (the tongue base TB and soft palate trailing end T are retained from movement toward the pharyngeal wall PW), the pressure (tension) is a counterforce pressure that prevents deformation of the external surface, the pressure is a counterforce pressure (tension) that creates an indentation in the external surface, or at least one of the retractor member (14), the shaft (12), and the anchor member (18) adjust to alter the pressure exerted on the soft tissue.

In regards to claim 51, Conrad et al. teaches the apparatus of claim 48. Conrad et al. teaches in column 3, lines 24-27 that the tissue retractor (14) is formed from one of more biocompatible materials (felt, PET).

In regards to claim 52, Conrad et al. teaches the apparatus of claim 48. Conrad et al. teaches in column 3, lines 29-30 that the shaft (12) is flexible (suture material).

In regards to claim 55, Conrad et al. teaches the apparatus of claim 48. Conrad et al. teaches in Figures 1 and 2 that the external surface can be the centerline of the tongue (T) curve.

In regards to claim 57, Conrad et al. teaches the apparatus of claim 48. Conrad et al. teaches in Figures 1 and 2 a connection to the patient's oral cavity.

In regards to claim 66, Conrad et al. teaches in Figures 1 and 2 and column 3, lines 24-33 and 48-51a shaft (12) configured for insertion into a patient's tongue (T); a retractor member (14) connected at or near a first end of the shaft (12), and an anchor member (18) connected at or near a second end of the shaft (12), wherein at least one of the retractor member (14) and the anchor member (18) is configured to be positioned on an external surface of the tongue (T), and at least one of the shaft (12), the retractor member (14) and the anchor member (18) prevents at least a portion of the tongue (T) from collapsing toward a soft tissue located in the patient's oral cavity or pharynx (the tongue base TB and soft palate trailing end T are retained from movement toward the pharyngeal wall PW).

In regards to claim 68, Conrad et al. teaches in Figures 1 and 2 and column 3, lines 24-33 and 48-51a shaft (12) sized for removable insertion through a patient's

tongue (T), the shaft (12) having a first end connected at or near the base of the tongue (TB) and a second end connected at or near the frenulum; a retractor member (14) connected at or near the first end; and an anchor member (18) connected at or near the second end, wherein the retractor member (14) is configured to be positioned on an external surface of the tongue (T), and the shaft (12), the retractor member (14) and the anchor member (18) interact to exert a counterforce pressure (tension) that prevents deformation of the external surface in a direction toward a soft tissue located in the patient's oral cavity or pharynx (the tongue base TB and soft palate trailing end T are retained from movement toward the pharyngeal wall PW).

In regards to claim 69, Conrad et al. teaches the apparatus of claim 68. Conrad et al. teaches in column 3, lines 48-51 that the counterforce pressure (tension) prevents the external surface from falling toward the soft tissue (the tongue base TB and soft palate trailing end T are retained from movement toward the pharyngeal wall PW).

In regards to claim 74, Conrad et al. teaches in Figures 1 and 2 and column 3, lines 24-33 and 48-51 the device having a first end, a second end, and a shaft (12) disposed therebetween, the shaft (12) is adapted to be disposed through a soft tissue (T) located in the patient's oral cavity or pharynx, with at least one of the first end and the second end being positioned on an external surface (the jaw bone JB) of the soft tissue (T) with each of the first end and the second end contacting solely soft tissue (T), and with at least one of the first end, the second end, and the shaft (12) interacting to exert a pressure (tension) that prevents deformation of at least a portion of the soft

tissue (T) to prevent obstruction in the patient's airway (the tongue base TB and soft palate trailing end T are retained from movement toward the pharyngeal wall PW).

In regards to claim 75, Conrad et al. teaches the apparatus of claim 74. Conrad et al. teaches in Figures 1 and 2 and column 3, line 37 that both the first and the second end are configured to be positioned on an external surface of the soft tissue (T), by adjusting the tension, and therefore, the length of the shaft (12).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 35, 37, 53, 56, 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conrad et al. (US patent 7,237,554).

In regards to claim 35, Conrad et al. teaches the apparatus of claim 32. Conrad et al. discloses the claim invention except for the shaft being removable. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the shaft removable, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlicnrnam*, 168 USPQ 177, 179.

In regards to claim 37, Conrad et al. teaches the apparatus of claim 32. Conrad et al. discloses the claim invention except for at least one of the retractor member and

the anchor member being disengagable from the shaft. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make at least one of the retractor member and the anchor member being disengagable from the shaft, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlicnrnam*, 168 USPQ 177, 179.

In regards to claim 53, Conrad et al. teaches the apparatus of claim 48. Conrad et al. discloses the claim invention except for the shaft being removable. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the shaft removable, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlicnrnam*, 168 USPQ 177, 179.

In regards to claim 56, Conrad et al. teaches the apparatus of claim 48. Conrad et al. discloses the claim invention except for at least one of the retractor member and the anchor member being disengagable from the shaft. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make at least one of the retractor member and the anchor member being disengagable from the shaft, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlicnrnam*, 168 USPQ 177, 179.

In regards to claim 67, Conrad et al. teaches the apparatus of claim 66. Conrad et al. discloses the claim invention except for the shaft being removable. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the shaft removable, since it has been held that constructing a formerly integral

structure in various elements involves only routine skill in the art. *Nerwin v. Erlicnrnam*, 168 USPQ 177, 179.

3. Claims 36, 38, 39, 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conrad et al. (US patent 7,237,554) in view of Boretos (US patent 4,254,774).

In regards to claim 36, Conrad et al. teaches the apparatus of claim 32. Conrad et al. does not teach that at least one of the retractor member, the shaft, and the anchor member comprises an inflatable tube. However, Boretos teaches in column 3, lines 21-27 and column 4, lines 34-35 an analogous device in which at least one of the retractor member, the shaft, and the anchor member comprises an inflatable tube (12). It would have been obvious to one having ordinary skill in the art at the time of invention to modify the retractor member, the shaft or the anchor taught by Conrad et al. with the inflatable tube taught by Boretos because this element is known to facilitate insertion and placement, as Boretos teaches in column 3, lines 21-27.

In regards to claim 38, Conrad et al. teaches the apparatus of claim 32. Conrad et al. does not teach that the shaft comprises an internal passageway for adding fluid. However, Boretos teaches in column 6, lines 30-33 an analogous device in which the shaft (11) comprises an internal passageway for adding fluid (gas). It would have been obvious to one having ordinary skill in the art at the time of invention to modify the shaft taught by Conrad et al. as modified by Boretos with the internal passageway for adding

fluid taught by Boretos because this element is known to provide for a change in shape of the shaft taught by Conrad et al., as Boretos teaches in column 5, lines 64-67.

In regards to claim 39, Conrad et al. and Boretos teach the apparatus of claim 32. Conrad et al. does not teach that the shaft comprises a regulator for said fluid. However, Boretos teaches in column 5, lines 64-67 and column 4, lines 30-33 an analogous device in which the shaft (11) comprises a regulator (21) for said fluid gas. It would have been obvious to one having ordinary skill in the art at the time of invention to modify the shaft taught by Conrad et al. as modified by Boretos with the regulator taught by Boretos because this element is known to control the change in shape and size produced by the influx of fluid into the shaft.

In regards to claim 54, Conrad et al. teaches the apparatus of claim 48. Conrad et al. does not teach that at least one of the retractor member, the shaft, and the anchor member comprises an inflatable tube, or that the shaft comprises an internal passageway for adding a fluid. However, Boretos teaches in column 6, lines 30-33 an analogous device in which the shaft (11) comprises an internal passageway for adding a fluid (gas). It would have been obvious to one having ordinary skill in the art at the time of invention to modify the shaft taught by Conrad et al. as modified by Boretos with the internal passageway for adding a fluid taught by Boretos because this element is known to provide for a change in shape of the shaft taught by Conrad et al., as Boretos teaches in column 5, lines 64-67.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA HICKS whose telephone number is (571)270-7033. The examiner can normally be reached on Monday through Thursday, 7:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/V. H./
Examiner, Art Unit 3772
11/2/09

/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772